



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JUN - 6 2000

1854 '00 JUN 28 P2:48

Mr. Neal J. Kane  
Vice President  
DCV, Inc.  
3521 Silverside Road  
Wilmington, Delaware 19810

Dear Mr. Kane:

This is in response to your letters of May 30, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that DCV, Inc. is making the following claims, among others, for the product Pylorex™ which is distributed by its subsidiary Legacy USA, Inc. (102 Harbor City Blvd., Melbourne, FL 32901):

“Helps your body reduce harmful intestinal bioburdens”

The product label also states that the product contains “active H. Pylori Antibodies” and names *Helicobacter pylori* in another place on the label.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, gastrointestinal diseases caused by pathogenic bacteria, such as *Helicobacter pylori*-induced conditions such as ulcers. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 373

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Philadelphia District Office, Office of Compliance, HFR-MA140  
FDA, Florida District Office, Office of Compliance, HFR-SE240

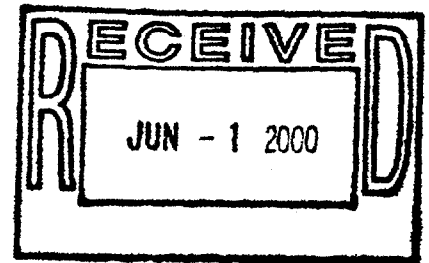
cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Barnett, Nickerson)  
f/t:HFS-811:rjm:6/1/00:docname:70945.adv:disc47



3521 Silverside Road  
Concord Plaza - Quillen Building  
Wilmington, Delaware 19810  
(302) 695-5502  
Fax: (302) 695-5350

May 30, 2000



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

RE: Notification of Dietary Supplement Marketing Claims

Dear Sir/Madam:

Pursuant to 21 CFR §101.93 this is to notify you that DCV, Inc. and its wholly owned subsidiary Legacy USA, Inc. will be marketing a dietary supplement containing the structure/function claims as indicated below.

1. Name and Address of Manufacturer and Distributor:

Manufacturer:

DCV, Inc.  
3521 Silverside Road  
Wilmington, DE 19810

Distributor:

Legacy USA, Inc.  
102 Harbor City Blvd.  
Melborne, FL 32901

2. Text of Statement:

The following statements will be made in marketing the product:

"This product:

- a) helps maintain a healthy gastrointestinal track,
- b) helps maintain a healthy intestinal flora,
- c) helps to support a healthy digestive track,
- d) helps support normal intestinal ecology for health,
- e) helps your body reduce harmful intestinal bioburdens."

Description of Dietary Ingredient or Supplement:

The product is a capsule formula with each serving (2 capsules per serving) containing 1000 mg of Egcel™, our patented, hyperimmunized egg powder.

70945

Providing Tomorrow's Innovative Solutions Today


4. Name of Dietary Supplement:

BioChoice® Pylorex™

5. Certification of Accuracy:

I, Neal Kane, Vice President of DCV, Inc. do hereby certify that the information contained in this notice is complete and accurate and that DCV, Inc. has substantiation that the statement to be made is truthful and not misleading.

mks

  
\_\_\_\_\_  
Neal J. Kane

Helicobacter pylori is a bacterium that prospers in the Gastrointestinal System. When used together with BioChoice® Immune Support, BioChoice® Pylorex™ helps to support a healthy digestive track\*.

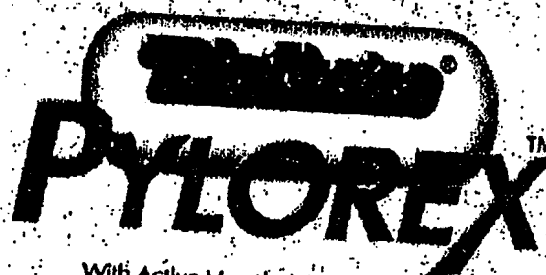
**Suggested Use:** Take two or more capsules daily.

**Caution:** If you are allergic to eggs, consult your healthcare professional before using this product.

Store in a cool dry place.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

#982177, #2522668



With Active H. pylori Antibodies\*

Dietary Supplement

60 Capsules

**Supplement Facts**  
Serving Size 2 Capsules

	Amount Per Serving	%Daily Values
EgCal™ (hyperimmunized egg powder)	1000 mg	*

\*Daily Value not established.

Other Ingredients: Dicalcium phosphate, gelatin and vegetable stearate.

Distributed by:

**LEGACY**

A BLEN CIPM ANI  
www.Biochoice.net

1035 Gateway Dr. #2005 Melbourne, FL 32901